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(71) Applicant *(for all designated States except US)*: **TAYSIDE UNIVERSITY HOSPITALS NHS TRUST** [GB/GB]; Ninewells Hospital, Dundee DD1 9SY (GB).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **RIX, Gerald, Henner** [GB/GB]: 9 Mackintosh Way, Perth PH1 1SL (GB).

(74) Agent: **MURGITROYD & COMPANY**; Scotland House, 165-169 Scotland Street, Glasgow, G5 8PL (GB).

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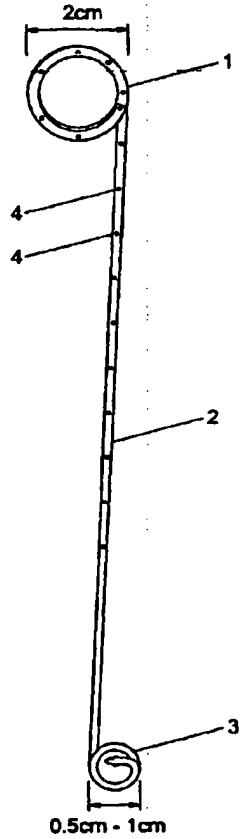
[Continued on next page]

(54) Title: STENT



(57) Abstract: There is provided an indwelling ureteral (ureteric) stent comprised of a hollow flexible tube with an upper end section, a substantially straight middle section and a lower end section. The upper and lower sections are preferably coiled. The coiled upper section has a diameter between 1 and 2.5 cm which retains the upper section of the stent in the kidney, and has perforations in the surface to allow drainage of urine from the kidney into the tube. The lower coiled section of the stent is G-shaped. The tip of this lower section assumes the horizontal portion of the G shape and contains an integral valve. The integral valve maintains an open flow of urine from the kidney to the bladder, but prevents the reflux of urine into the kidney during bladder contraction. The stent further comprises a small cuff or series of studs behind said valve against which a stent pusher may rest.

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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/04 A61M25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	WO 99 09911 A (UROSURGE INC) 4 March 1999 (1999-03-04) page 9, line 22 -page 10, line 24; figures page 5, line 10 -page 6, line 6	1,13,14, 16-19 4,5,7,8
X	US 4 225 979 A (REY PIERRE ET AL) 7 October 1980 (1980-10-07) column 3, line 65 -column 6, line 11; figures	1
A	EP 0 208 841 A (INTERMEDICAT GMBH) 21 January 1987 (1987-01-21) column 2, line 45 -column 4, line 4; figures	1-6
A	US 4 307 723 A (FINNEY ROY P) 29 December 1981 (1981-12-29) column 5, line 34 - line 44; figures	1

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 October 2001	29. 11. 2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Kousouretas, I

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 354 263 A (COLL MILTON E) 11 October 1994 (1994-10-11)	10-12
A	column 3, line 60 -column 6, line 3; figures	4,13,14, 16-21
X	US 4 931 037 A (WETTERMAN PETER H) 5 June 1990 (1990-06-05)	10,11
A	abstract; figures	4,5
A	US 5 141 502 A (MACALUSO JR JOSEPH N) 25 August 1992 (1992-08-25) column 3, line 36 - line 51; figures	4,5,10, 11
A	US 5 941 823 A (CHAIT PETER G) 24 August 1999 (1999-08-24) abstract; figures	4,5
P,X	EP 1 051 989 A (KARBIX ESTABLISHMENT) 15 November 2000 (2000-11-15)	10-12
A	the whole document	4,13,14, 17-19

INTERNATIONAL SEARCH REPORT

ational application No.
PCT/GB 01/02323

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [X] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

[X] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-3

An indwelling ureteral stent comprising an elongated tubular body, an upper end section, a straight middle section and a lower end section wherein the tip of the lower end section of the stent comprises a valve as an integral part of the flexible material comprising the stent.

2. Claims: 4-9

An indwelling ureteral stent comprising an elongated tubular body, an upper end section, a straight middle section and a lower end section wherein the upper lower section forms a closed loop such that the tip of the end section of the stent is not exposed.

3. Claims: 10-12

An indwelling ureteral stent comprising an elongated tubular body, an upper end section, a straight middle section and a lower end section wherein the flexible material decreases in external diameter from the upper end section to the lower end section.

4. Claims: 13-22

An indwelling ureteral stent comprising an elongated tubular body, an upper end section, a straight middle section and a lower end section wherein the stent further comprises at least one projection against which a stent pusher may rest.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
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(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

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(54) Title: STENT

(57) Abstract: There is provided an indwelling ureteral (ureteric) stent comprised of a hollow flexible tube with an upper end section, a substantially straight middle section and a lower end section. The upper and lower sections are preferably coiled. The coiled upper section has a diameter between 1 and 2.5 cm which retains the upper section of the stent in the kidney, and has perforations in the surface to allow drainage of urine from the kidney into the tube. The lower coiled section of the stent is G-shaped. The tip of this lower section assumes the horizontal portion of the G shape and contains an integral valve. The integral valve maintains an open flow of urine from the kidney to the bladder, but prevents the reflux of urine into the kidney during bladder contraction. The stent further comprises a small cuff or series of studs behind said valve against which a stent pusher may rest.

STENT

The present invention relates to an indwelling ureteral (ureteric) stent which exhibits improved anti-reflux properties and which also reduces bladder irritation.

Ureteral stents are used in endo-urological intervention on a daily basis to allow drainage of urine from the kidneys to the bladder in instances of actual or potential ureteral obstruction. Such instances include ureteral injury due to trauma, obstructive uropathy such as kidney stones, and following surgery in the upper or lower urinary tracts.

Generally, stents are comprised of a hollow tube made of flexible material, of length varying from 25-35cm with an external diameter from about 1.5-3mm and an internal diameter of about 0.5-2mm. Both ends are curled, forming spirals which produce an 'O' shape at each end of the stent. This allows the

upper end to be retained within the kidney and the lower end within the bladder, thus preventing movement after placement. The flexibility of the comprising material allows the stent to conform to any curves of the ureter and also allows placement and removal through narrow urological instruments placed by means of the urethra. Currently the commonest form of stent used is known as a Double J Stent, or Double Pigtail Stent.

There are several problems for the patient associated with the use of the stents. Specifically, these are that during voiding of the bladder, the increased intravesical pressure, which induces evacuation of the bladder, can result in a back flow or reflux of urine. The hollow tube construction allows urine to pass up the stent producing pressure in the kidney as the bladder contracts during urination. These events are known as reflux.

Urine passing from the kidney to the bladder is sterile. If however, the urine becomes contaminated in the lower urinary tract with infection by pyrogenic organisms, then reflux of this urine may result in the development of sepsis, which can damage the kidney and also have potentially lethal consequences for the patient. The risk of sepsis following the employment of an indwelling stent between the kidney and the bladder, means that there is a need to provide a ureteral stent which will maintain an open flow of urine from the kidney to

the bladder, while also inhibiting the reflux of urine to the kidney.

Further, during bladder evacuation, the stent may retract into the ureteral orifice. This upwards migration of the stent is seen with many stents of the mono J stent type, wherein the lower end of the stent doesn't have a curl.

A further problem associated with the use of stents is that the lower coil irritates the bladder by touching its lining. This is usually caused by the volume of material comprising the lower coil as well as the tip of the lower coil digging into the bladder lining.

Presently in the field, there are a number of stents which try to overcome the problems associated with the use of such devices, these are outlined below:

Anti-Reflux Stents

An article by Ahmadzadeh (Stenting the Urinary System. D Yachia. ISBN 1899066829) discloses a Double Pigtail Stent with a transparent thin walled segment made of polyurethane which is designed to lie at the junction between the ureter and the bladder i.e. at the vesico-ureteric junction. The floppy polyurethane walls would co-apt with vesical pressure rise preventing reflux. They would also allow the slit like ureteric orifice, which is a natural valve, to remain closed during intra-vesical

pressure rises, which is how reflux is prevented in the normal healthy ureter and bladder.

United States Patent No 5019102 discloses a valve system comprising two thin transparent membranes forming a bag open at the distal end attached to the lower end of an ordinary stent and again as the pressure rises within the bladder these are pressured together preventing reflux of fluid.

Conversely when urine needs to be excreted, they open out allowing fluid drainage into the bladder.

United States Patent No 564783 teaches of a Double J Stent with a closed lower portion which does not allow urine to drain up or down it and therefore prevents reflux. The lower end also has a small side hole into which the tip of the lower end curls back into after stent placement this being aided by two magnets.

Stents to Reduce Bladder Irritation

United States Patent No 5141502 discloses a stent with a helical upper end and a lower end made of a softer, non-irritating material but containing a cuff at the level of the vesico-ureteric junction, which allows placement over a guide wire.

A stent with a softer coil at the lower end bonded on to reduce bladder irritation is described in US Patent No 4931037.

International Patent Application No WO 9717094 teaches of a stent with a lower portion which tails off into a thinner flexible region whose small diameter reduces bladder irritation and also does not push open the vesico-ureteric junction to such an extent, but which is not hollow so no longer acts as a channel for urine drainage either.

It is an object of the present invention to provide an improved indwelling ureteric stent to provide drainage between the kidney and the bladder. It is a further object of the invention to prevent the reflux of urine from the bladder into the kidney, thereby preventing flank pain associated with voiding and also the passage of infected urine in the lower urinary tract into the kidney where this could cause damage to the upper urinary tract. A further aim of the present invention serves to reduce the irritation of the bladder, which is associated with the use of stents.

According to a first aspect of the present invention there is provided an indwelling ureteral stent constructed of flexible material which comprises a hollow elongated tubular body, said hollow elongated tubular body comprising an upper end section, a substantially straight middle section and a lower end section wherein the tip of the lower end section of the stent comprises a valve which permits the hollow body to be in an open or a closed position

wherein the valve is an integral part of the flexible material comprising the stent.

More preferably the valve is a bicuspid valve having two leaflets or a tricuspid valve having three leaflets.

Most preferably the valve is a bicuspid valve.

In a preferred embodiment the valve is provided through the moulded interlay of the flexible material such that in the closed position at rest the leaflets of the valve lie flat against each other providing a seal which prevents urine passing up the stent.

A second aspect of the present invention relates to an indwelling ureteral stent constructed of flexible material which comprises a hollow elongated tubular body, said hollow elongated body comprising an upper coiled section, a substantially straight middle section, and a lower end section wherein the lower section forms a closed or substantially closed loop, such that in use the tip of the end section of the stent is not exposed and cannot contact the bladder lining.

Preferably the stent also comprises a valve as described herein.

Preferably the lower end section is "G" shaped or spherically shaped such that in use the tip of the

end section will not contact the lining of the bladder.

Preferably the upper section comprises a coil, said coil including flexible material between 6 to 15cm of flexible material coiled once or twice upon itself, said coil having a diameter between 1 and 2.5cm.

Preferably the lower section comprises a coil, said coil including a flexible material wherein said material is coiled thus forming an "O" or a "G" shape with a diameter of between 0.5-2cm and wherein the tip of the stent rests within the coil and therefore, in use does not contact the bladder lining.

More preferably the lower section is formed into a "G" shape such that the tip of the stent assumes the horizontal portion of the G shape.

A third aspect of the present invention relates to an indwelling ureteral stent constructed of flexible material which substantially comprises a hollow elongated tubular body, said hollow elongated tubular body comprising an upper end section, a substantially straight middle section and a lower end section wherein the flexible material decreases in external diameter from the upper end section to the lower end section such that there is maximum drainage in the upper urinary tract and minimum irritation in the lower urinary tract.

Preferably the stent also comprises a valve as described herein the lower end shaped as described herein to prevent contact of the valve in the tip with the bladder lining.

More preferably the flexible material is tapered in diameter towards the lower end, such that the lower third of the substantially straight middle section and the totality of the lower section are of a reduced diameter.

A fourth aspect of the present invention relates to an indwelling ureteral stent constructed of flexible material which comprises a hollow elongated tubular body, said hollow elongated tubular body comprising an upper end section, a substantially straight middle section and a lower end section, wherein the stent further comprises at least one projection against which a stent pusher may rest.

Preferably the stent also comprises a valve as described herein and / or at least one end of the stent is shaped as described herein to prevent contact of the tip with the bladder lining.

Preferably the stent is tapered as described herein.

Preferably the projection(s) form a cuff.

Preferably the projection(s) consist of a plurality of studs.

According to each aspect of the invention the flexible material of the stent may comprise any composition which forms a hollow tube.

The flexible material may have a cylindrical cross section.

Alternatively the flexible material may have any shape of cross section either throughout it's whole length or in one section alone, such as in the lower third alone, including a spiral, a star or an oval, especially wherein said shape facilitates drainage on the outer surface or accommodation to the natural contours of the urinary tract preventing reflux around the stent.

Preferably the flexible material of said stent has an external diameter in the range 1mm to 5mm.

More preferably the flexible material of said stent has as external diameter in the range 1.5mm to 3mm.

Preferably the flexible material of said stent is sof flex™, endo sof™ or ultrathane™.

The invention is further described with reference to the following figures wherein:

Figure 1 illustrates a preferred embodiment of the stent

Figure 2 illustrates the G shaped coil

Figure 3 illustrates the integral valve

Figures 3 and 4 illustrate the projections against which a stent pusher can rest.

In one specific embodiment the invention provides a stent which consists of a single piece of flexible material which can be of any suitable composition in that the material forms a hollow tube such as sof flex™, endo sof™ or ultrathane™. This tube is moulded into an upper coil (1) a straight segment (2) and a lower coil (3). Figure 1 is a representation of such a stent. A cross section of the stent is typically cylindrical but may also be modified into any shape in cross section either throughout it's whole length or in one section alone such as in the lower third alone (such as a spiral, a star shape or an oval) to facilitate drainage around the outside of the stent or alternatively to aid passage through the urinary anatomy during the placement procedure or allow accommodation to the natural contours of the urinary tract preventing reflux around the stent.

The diameter of the cylinder can be of any size but externally would be from about 1.5-3mm (usually 1.9mm ie. 6 French gauge) with an internal diameter of about 0.5-2.0mm in the upper coil (1), typically 0.9mm. This diameter can be maintained throughout the length of the whole stent.

In a further embodiment of the present invention the diameter of 6 French gauge (1.9mm) may be only maintained for the upper two thirds of the middle segment (2). The diameter then tapers to a diameter of 1.5mm (4.7 French gauge) in the lower third of the middle segment (2) and the lower coil (3).

In both embodiments of the present invention described above, the upper coil (1) will use about 6-15cm of material coiled once or twice upon itself over a diameter of about 1 to 2.5cm. It will allow significant uncoiling during placement to adjust for varying lengths of ureters in different patients.

The middle segment (2) will generally be about 22cm long, but may be varied to the approximate length of the patients ureter and both it and the upper coil (1) will have small perforations at regular intervals (4) allowing the passage of urine from the outside to the inside of the stent and vice-versa. These perforations will stop in the lower third of the straight segment to avoid reflux in and below this area.

The lower coil (3) is made up of about 4 to 5cm of material coiled into a smaller diameter curl of either 1.5cm if it maintains the diameter of a 6 French gauge throughout its entirety or 1cm if it tapers to 4.7 French gauge size. This coil will have a G-shape such that the end of the stent forms the horizontal part of the G. Representations of

such a coil are shown in Figure 2. The G-shape formation of the lower coil prevents the distal tip of the stent touching other parts of the stent and impeding the free action of the valve on this end. It also prevents the end of the stent digging into and irritating the bladder. As mentioned above, this part of the stent is of a smaller diameter (usually 1.5mm ie. 4.7 French gauge) to reduce bladder irritation. The tip of the lower end of the stent is cut and moulded to form a valve (6,7,8), which may be of any kind, but will preferably be of a bicuspid or tricuspid type. Representations illustrating embodiments of the valve as bicuspid and tricuspid types are shown in Figure 3. In a preferred embodiment a bicuspid valve may be provided through moulded interlay of the material comprising the stent, such that in the resting position the 2 leaflets of the valve lie flat against each other providing a seal which prevents urine passing up the stent.

In the stent whose G has diameter of 6 French gauge or 1.9mm in size, the length of the valve will be 7mm.

In the further embodiment of the present invention in which the diameter tapers down to 4.7 French gauge or 1.5mm in size, the valve itself will be 5mm long.

The valve leaflets will easily be pushed apart by urine passing down the stent or the guide wire onto which the stent is fed during placement.

Located about 3mm behind the valve in both 6 French gauge (1.9mm) and 4.7 French gauge (1.5mm) is a small cuff, or four studs (12) which are again moulded out of the flexible material. This cuff or four studs (12) is used for the stent pusher to rest against when placing the stent over a flexible metal guide wire, this is shown in Figure 4.

Placement of the stent is facilitated by means of a conventional cystoscope using a conventional guide wire (11) passed through the urethra into the bladder, through the ureteric orifice up the ureter and into the renal pelvis under fluoroscopic control. The stent is fed onto the guide wire with the upper coil first and then pushed into place using a modified conventional stent pusher (10) which fits over the valve and rests against the cuff just behind the valve at the lower curl, thereby minimising trauma to the valve on insertion. Once the stent is in place the guide wire and stent pusher are removed.

Removal of the stent would be through the urethra using a cystoscope or alternatively from above either at the time of surgery on the kidney or with percutaneous retrieval devices.

1) Holes in the upper two thirds of the stent allow maximum drainage in and out of the stent to overcome any upper ureteric obstruction. The lack of perforations in the lower third and lower coil prevent reflux.

2) The tapering arrangement whereby the tube decreases in external diameter from 1.9mm (6 French gauge) at the upper diameter to 1.5mm (4.7 French gauge) lower diameter allows maximum drainage in the upper urinary tract and minimum irritation in the lower urinary tract.

3) The small size of the lower coil causes less bladder irritation than conventional stents.

4) The assumption of a G-shape of the lower coil ensures that the end of the stent which is normally free to dig into the bladder does not do this, thereby minimising stent induced irritation, which can itself produce unstable bladder contractions and secondary reflux of urine.

5) The advantage of the herein described valve over existing valves is that the present valve is an integral part of the stent rather than being stuck on, therefore there is virtually no risk of a piece of the stent falling off or becoming partially detached from the main body of the stent as a retained foreign body. It is also much smaller than existing polythene bag

valves and should therefore cause less bladder irritation.

The present invention can be inserted into patients using a traditional procedure as described above.

CLAIMS

1. An indwelling ureteral stent constructed of flexible material which comprises a hollow elongated tubular body, said hollow elongated tubular body comprising an upper end section, a substantially straight middle section and a lower end section wherein the tip of the lower end section of the stent comprises a valve which permits the hollow body to be in an open or a closed position wherein the valve is an integral part of the flexible material comprising the stent.

2. An indwelling ureteral stent as claimed in any of the preceding claims wherein the valve is a bicuspid valve having two leaflets or a tricuspid valve having three leaflets.

3. An indwelling ureteral stent as claimed in any of the preceding claims wherein the valve is provided through the moulded interlay of the flexible material such that in the closed position the leaflets of the valve lie flat against each other providing a seal which prevents urine passing up the stent.

4. An indwelling ureteral stent constructed of flexible material which comprises a hollow elongated tubular body, said hollow elongated body comprising an upper section, a substantially straight middle section, and a

lower end section wherein the upper lower section forms a closed or substantially closed loop, such that in use the tip of the end section of the stent is (are) not exposed and cannot contact the bladder lining.

5. An indwelling ureteral stent as claimed in any of the preceding claims wherein the upper and lower end sections form closed or substantially closed loops.

6. An indwelling ureteral stent as claimed in any of the preceding claims wherein the lower end section is "G" shaped or spherically shaped such that in use the tip of the end section will not contact the bladder lining.

7. An indwelling ureteral stent as claimed in any of the preceding claims wherein the upper section comprises a coil, said coil including flexible material between 6 to 15cm coiled once or twice upon itself, said coil having a diameter between 1 and 2.5cm.

8. An indwelling ureteral stent as claimed in any of the preceding claims wherein the lower section comprises a coil, said coil including a flexible material wherein said material is coiled thus forming an "O" or a "G" shape with a diameter of between 0.5-2cm.

9. An indwelling ureteral stent as claimed in any

of the preceding claims wherein the lower section is formed into a "G" shape such that the tip of the stent assumes the horizontal portion of the G shape.

10. An indwelling ureteral stent constructed of flexible material which substantially comprises a hollow elongated tubular body, said hollow elongated tubular body comprising an upper end section, a substantially straight middle section and a lower end section wherein the flexible material decreases in external diameter from the upper end section to the lower end section such that there is maximum drainage in the upper urinary tract and minimum irritation in the lower urinary tract.

11. An indwelling ureteral stent as claimed in any of the preceding claims wherein the flexible material decreases in external diameter from the upper end section to the lower end section.

12. An indwelling ureteral stent as claimed in any of the preceding claims wherein the flexible material is tapered in diameter towards the lower end, such that the lower third of the substantially straight middle section and the totality of the lower section are of a reduced diameter.

13. An indwelling ureteral stent constructed of flexible material which comprises a hollow

elongated tubular body, said hollow elongated tubular body comprising an upper end section, a substantially straight middle section and a lower end section, wherein the stent further comprises at least one projection against which a stent pusher may rest.

14. An indwelling ureteral stent as claimed in any of the preceding claims wherein the stent further comprises at least one projection against which a stent pusher may rest.

15. An indwelling ureteral stent as claimed in claims 13 or 14 wherein the projection(s) form a cuff.

16. An indwelling ureteral stent as claimed in claims 13 to 15 wherein the projection(s) consist of a plurality of studs.

17. An indwelling ureteral stent as claimed in any of the preceding claims wherein the flexible material includes any composition which forms a hollow tube.

18. An indwelling ureteral stent as claimed in any of the preceding claims wherein the flexible material has a cylindrical cross section.

19. An indwelling ureteral stent as claimed in any of the preceding claims wherein the flexible material has any shape of cross section,

including a spiral, a star or an oval, especially wherein said shape facilitates drainage on the outer surface.

20. An indwelling ureteral stent as claimed in any of the preceding claims wherein the flexible material of said stent has an external diameter in the range 1mm to 5mm.

21. An indwelling ureteral stent as claimed in any of the preceding claims wherein the flexible material of said stent has an external diameter in the range 1.5mm to 3mm.

22. An indwelling ureteral stent as claimed in any of the preceding claims wherein the flexible material is sof flex™, endo sof™ or ultrathane™.

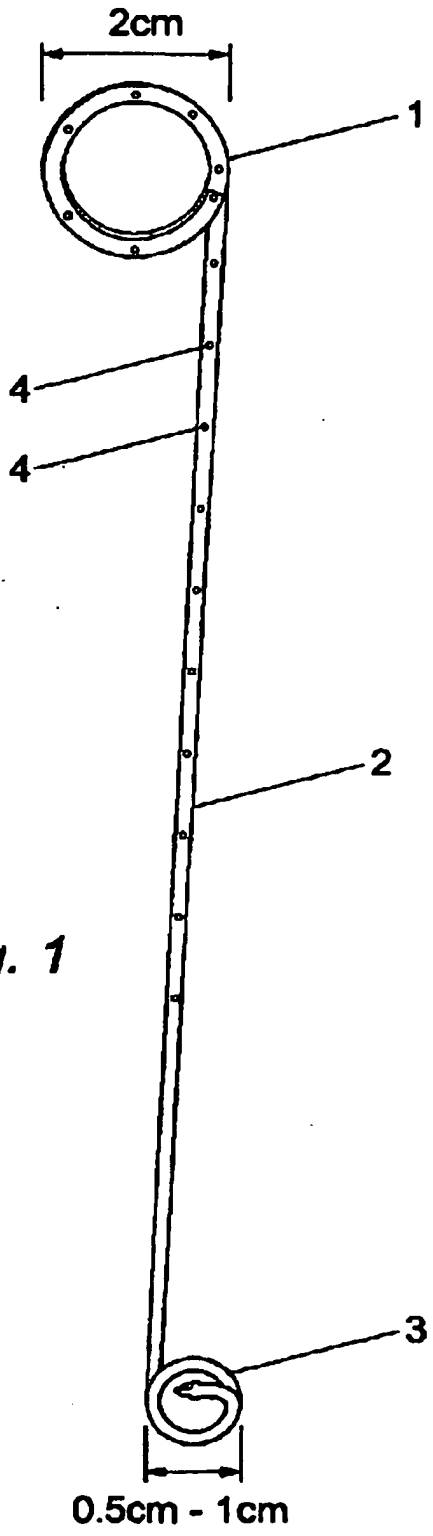

Fig. 1

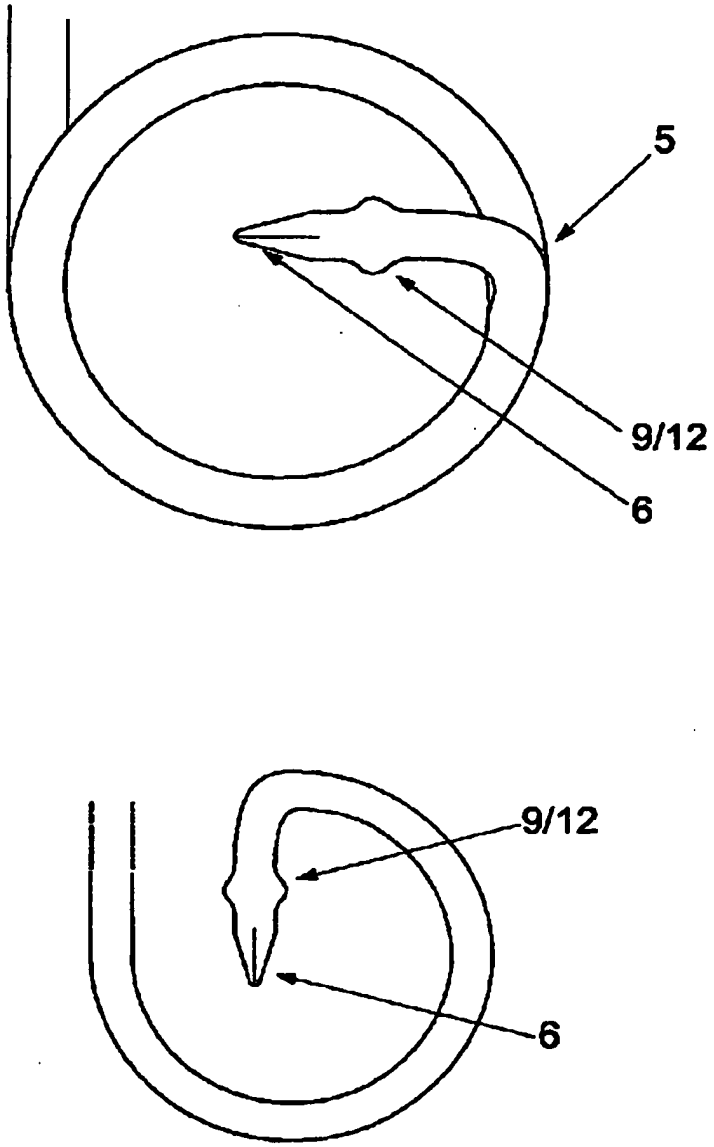

Fig. 2

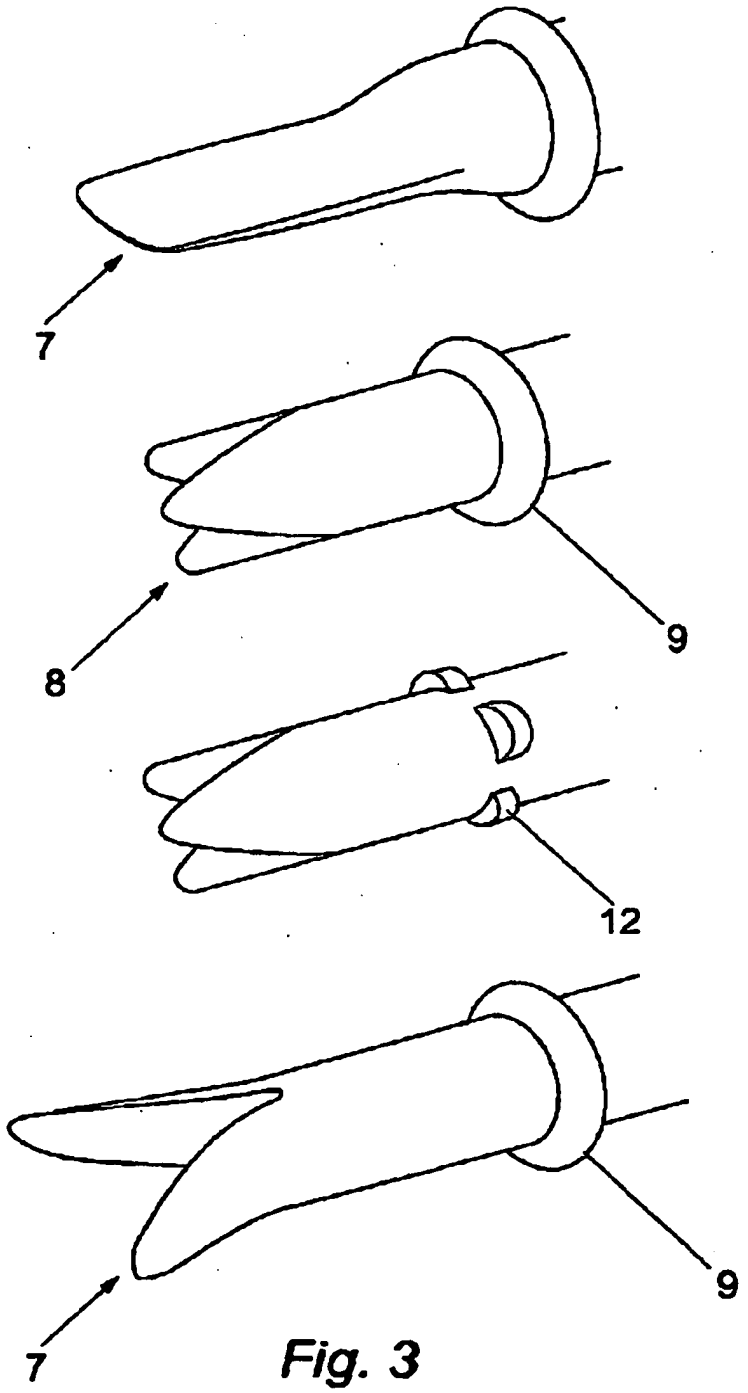

Fig. 3

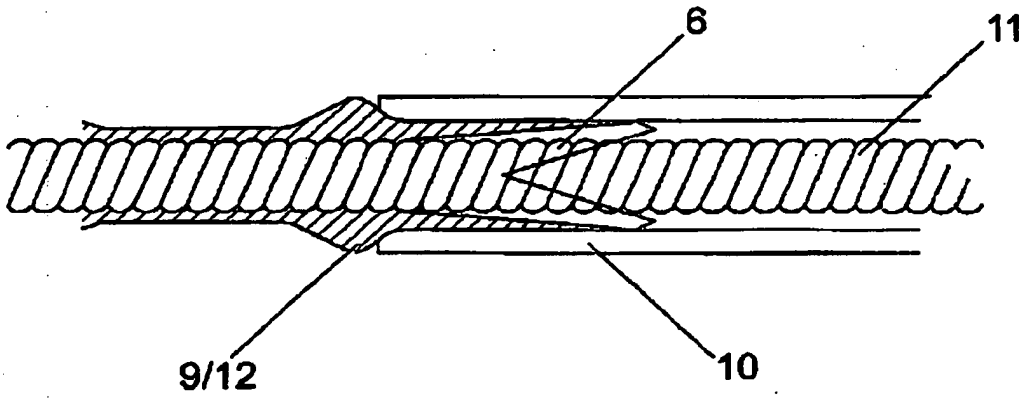

Fig. 4

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
P25453A/RMC		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/GB 01/02323	25/05/2001	26/05/2000
Applicant		
TAYSIDE UNIVERSITY HOSPITALS NHS TRUST et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the International search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [X] **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 1

   [ ] as suggested by the applicant.

   [X] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

   [ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 01/02323

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-3

An indwelling ureteral stent comprising an elongated tubular body, an upper end section, a straight middle section and a lower end section wherein the tip of the lower end section of the stent comprises a valve as an integral part of the flexible material comprising the stent.

2. Claims: 4-9

An indwelling ureteral stent comprising an elongated tubular body, an upper end section, a straight middle section and a lower end section wherein the upper lower section forms a closed loop such that the tip of the end section of the stent is not exposed.

3. Claims: 10-12

An indwelling ureteral stent comprising an elongated tubular body, an upper end section, a straight middle section and a lower end section wherein the flexible material decreases in external diameter from the upper end section to the lower end section.

4. Claims: 13-22

An indwelling ureteral stent comprising an elongated tubular body, an upper end section, a straight middle section and a lower end section wherein the stent further comprises at least one projection against which a stent pusher may rest.

INTERNATIONAL SEARCH REPORT

International Application No
GB 01/02323

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/04 A61M25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	WO 99 09911 A (UROSURGE INC) 4 March 1999 (1999-03-04) page 9, line 22 -page 10, line 24; figures page 5, line 10 -page 6, line 6	1,13,14, 16-19 4,5,7,8
X	US 4 225 979 A (REY PIERRE ET AL) 7 October 1980 (1980-10-07) column 3, line 65 -column 6, line 11; figures	1
A	EP 0 208 841 A (INTERMEDICAT GMBH) 21 January 1987 (1987-01-21) column 2, line 45 -column 4, line 4; figures	1-6
A	US 4 307 723 A (FINNEY ROY P) 29 December 1981 (1981-12-29) column 5, line 34 - line 44; figures	1

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

'A' document defining the general state of the art which is not considered to be of particular relevance

'E' earlier document but published on or after the international filing date

'L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

'O' document referring to an oral disclosure, use, exhibition or other means

'P' document published prior to the international filing date but later than the priority date claimed

'T' later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

'X' document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

'Y' document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

'&' document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 October 2001	29. 11. 2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Kousouretas, I

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
GB 01/02323

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 354 263 A (COLL MILTON E) 11 October 1994 (1994-10-11)	10-12
A	column 3, line 60 -column 6, line 3; figures	4,13,14, 16-21
X	US 4 931 037 A (WETTERMAN PETER H) 5 June 1990 (1990-06-05)	10,11
A	abstract; figures	4,5
A	US 5 141 502 A (MACALUSO JR JOSEPH N) 25 August 1992 (1992-08-25) column 3, line 36 - line 51; figures	4,5,10, 11
A	US 5 941 823 A (CHAIT PETER G) 24 August 1999 (1999-08-24) abstract; figures	4,5
P,X	EP 1 051 989 A (KARBIX ESTABLISHMENT) 15 November 2000 (2000-11-15)	10-12
A	the whole document	4,13,14, 17-19

3

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
GB 01/02323

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 9909911	A	04-03-1999	US	5984965 A	16-11-1999
			AU	9121798 A	16-03-1999
			WO	9909911 A2	04-03-1999
			ZA	9807814 A	01-03-1999
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			DE	2851010 A1	31-05-1979
			GB	2011260 A ,B	11-07-1979
			JP	1390311 C	23-07-1987
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			DE	3681520 D1	24-10-1991
			EP	0208841 A2	21-01-1987
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			CA	1112119 A1	10-11-1981
			DE	2905703 A1	11-10-1979
			DE	7904093 U1	08-04-1982
			FR	2421625 A1	02-11-1979
			GB	2018600 A ,B	24-10-1979
US 5354263	A	11-10-1994	US	5116309 A	26-05-1992
			US	5221253 A	22-06-1993
			US	5364340 A	15-11-1994
			US	5346467 A	13-09-1994
US 4931037	A	05-06-1990	NONE		
US 5141502	A	25-08-1992	NONE		
US 5941823	A	24-08-1999	US	5727555 A	17-03-1998
			US	6223070 B1	24-04-2001
EP 1051989	A	15-11-2000	EP	1051989 A2	15-11-2000

Copy for the Elected Office (EO/US) PCT/GB01/02323

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

MURGITROYD & COMPANY
Scotland House
165-169 Scotland Street
Glasgow, G5 8PL
ROYAUME-UNI

Date of mailing (day/month/year)
30 January 2002 (30.01.02)

Applicant's or agent's file reference
P25453A/RMC

IMPORTANT NOTIFICATION

International application No.
PCT/GB01/02323

International filing date (day/month/year)
25 May 2001 (25.05.01)

1. The following indications appeared on record concerning:

[ ] the applicant [ ] the inventor [X] the agent [ ] the common representative

Name and Address
MURGITROYD & COMPANY
373 Scotland Street
Glasgow G5 8QA
United Kingdom

State of Nationality
State of Residence
Telephone No.
0141 307 8400
Facsimile No.
0141 307 8401
Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[ ] the person [ ] the name [X] the address [ ] the nationality [ ] the residence

Name and Address
MURGITROYD & COMPANY
Scotland House
165-169 Scotland Street
Glasgow, G5 8PL
United Kingdom

State of Nationality
State of Residence
Telephone No.
0141 307 8400
Facsimile No.
0141 307 8401
Teleprinter No.

3. Further observations, if necessary:
The new address on the demand has been considered as a change of address under Rule 92bis. In case of a disagreement the International Bureau should be notified immediately.

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[X] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

Authorized officer
Sylvaine DESCLOUX
Telephone No.: (41-22) 338.83.38

Form PCT/IB/306 (March 1994)

004628777

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING DOCUMENT TRANSMITTED

To:

Commissioner
US Department of Commerce
United States Patent and Trademark Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE
in its capacity as designated Office

Date of mailing (day/month/year)	
29 November 2001 (29.11.01)	
International application No.	International filing date (day/month/year)
PCT/GB01/02323	25 May 2001 (25.05.01)
Applicant	
TAYSIDE UNIVERSITY HOSPITALS NHS TRUST et al	

The International Bureau transmits herewith the following documents and number thereof:

_____ copy(ies) of declaration(s) (Rule 47.1(a-ter))

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

M. OUCHOUKHI

Telephone No.: (41-22) 338.83.38

PCT/GB01/02323

PATENT COOPERATION TREA

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 30 January 2002 (30.01.02)	
International application No. PCT/GB01/02323	Applicant's or agent's file reference P25453A/RMC
International filing date (day/month/year) 25 May 2001 (25.05.01)	Priority date (day/month/year) 26 May 2000 (26.05.00)
Applicant RIX, Gerald, Henner	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

24 December 2001 (24.12.01)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Sylvaine DESCLOUX
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

Form PCT/IB/331 (July 1992)

GB0102323

CLAIMS

1. An indwelling ureteral stent constructed of flexible material which comprises a hollow elongated tubular body, said hollow elongated tubular body comprising an upper end section, a substantially straight middle section and a lower end section wherein the tip of the lower end section of the stent comprises a valve which permits the hollow body to be in an open or a closed position wherein the valve is an integral part of the flexible material comprising the stent.

2. An indwelling ureteral stent as claimed in any of the preceding claims wherein the valve is a bicuspid valve having two leaflets or a tricuspid valve having three leaflets.

3. An indwelling ureteral stent as claimed in any of the preceding claims wherein the valve is provided through the moulded interlay of the flexible material such that in the closed position the leaflets of the valve lie flat against each other providing a seal which prevents urine passing up the stent.

4. An indwelling ureteral stent constructed of flexible material which comprises a hollow elongated tubular body, said hollow elongated body comprising an upper section, a substantially straight middle section, and a

lower end section wherein the upper lower section forms a closed or substantially closed loop, such that in use the tip of the end section of the stent is (are) not exposed and cannot contact the bladder lining.

5. An indwelling ureteral stent as claimed in any of the preceding claims wherein the upper and lower end sections form closed or substantially closed loops.

6. An indwelling ureteral stent as claimed in any of the preceding claims wherein the lower end section is "G" shaped or spherically shaped such that in use the tip of the end section will not contact the bladder lining.

7. An indwelling ureteral stent as claimed in any of the preceding claims wherein the upper section comprises a coil, said coil including flexible material between 6 to 15cm coiled once or twice upon itself, said coil having a diameter between 1 and 2.5cm.

8. An indwelling ureteral stent as claimed in any of the preceding claims wherein the lower section comprises a coil, said coil including a flexible material wherein said material is coiled thus forming an "O" or a "G" shape with a diameter of between 0.5-2cm.

9. An indwelling ureteral stent as claimed in any

of the preceding claims wherein the lower section is formed into a "G" shape such that the tip of the stent assumes the horizontal portion of the G shape.

10. An indwelling ureteral stent constructed of flexible material which substantially comprises a hollow elongated tubular body, said hollow elongated tubular body comprising an upper end section, a substantially straight middle section and a lower end section wherein the flexible material decreases in external diameter from the upper end section to the lower end section such that there is maximum drainage in the upper urinary tract and minimum irritation in the lower urinary tract.

11. An indwelling ureteral stent as claimed in any of the preceding claims wherein the flexible material decreases in external diameter from the upper end section to the lower end section.

12. An indwelling ureteral stent as claimed in any of the preceding claims wherein the flexible material is tapered in diameter towards the lower end, such that the lower third of the substantially straight middle section and the totality of the lower section are of a reduced diameter.

13. An indwelling ureteral stent constructed of flexible material which comprises a hollow

elongated tubular body, said hollow elongated tubular body comprising an upper end section, a substantially straight middle section and a lower end section, wherein the stent further comprises at least one projection against which a stent pusher may rest.

14. An indwelling ureteral stent as claimed in any of the preceding claims wherein the stent further comprises at least one projection against which a stent pusher may rest.

15. An indwelling ureteral stent as claimed in claims 13 or 14 wherein the projection(s) form a cuff.

16. An indwelling ureteral stent as claimed in claims 13 to 15 wherein the projection(s) consist of a plurality of studs.

17. An indwelling ureteral stent as claimed in any of the preceding claims wherein the flexible material includes any composition which forms a hollow tube.

18. An indwelling ureteral stent as claimed in any of the preceding claims wherein the flexible material has a cylindrical cross section.

19. An indwelling ureteral stent as claimed in any of the preceding claims wherein the flexible material has any shape of cross section,

including a spiral, a star or an oval, especially wherein said shape facilitates drainage on the outer surface.

20. An indwelling ureteral stent as claimed in any of the preceding claims wherein the flexible material of said stent has an external diameter in the range 1mm to 5mm.

21. An indwelling ureteral stent as claimed in any of the preceding claims wherein the flexible material of said stent has an external diameter in the range 1.5mm to 3mm.

22. An indwelling ureteral stent as claimed in any of the preceding claims wherein the flexible material is sof flex™, endo sof™ or ultrathane™.

The valve leaflets will easily be pushed apart by urine passing down the stent or the guide wire onto which the stent is fed during placement.

Located about 3mm behind the valve in both 6 French gauge (1.9mm) and 4.7 French gauge (1.5mm) is a small cuff, or four studs (12) which are again moulded out of the flexible material. This cuff or four studs (12) is used for the stent pusher to rest against when placing the stent over a flexible metal guide wire, this is shown in Figure 4.

Placement of the stent is facilitated by means of a conventional cystoscope using a conventional guide wire (11) passed through the urethra into the bladder, through the ureteric orifice up the ureter and into the renal pelvis under fluoroscopic control. The stent is fed onto the guide wire with the upper coil first and then pushed into place using a modified conventional stent pusher (10) which fits over the valve and rests against the cuff just behind the valve at the lower curl, thereby minimising trauma to the valve on insertion. Once the stent is in place the guide wire and stent pusher are removed.

Removal of the stent would be through the urethra using a cystoscope or alternatively from above either at the time of surgery on the kidney or with percutaneous retrieval devices.

Box No. VIII (iv) DECLARATION: INVENTORSHIP (only for the purposes of the designation of the United States of America)

The declaration must conform to the following standardized wording provided for in Section 214; see Notes to Boxes Nos. VIII, VIII (i) to (v) (in general) and the specific Notes to Box No. VIII (iv). If this Box is not used, this sheet should not be included in the request.

Declaration of inventorship (Rules 4.17(iv) and 51*bis*.1(a)(iv)) for the purposes of the designation of the United States of America:

I hereby declare that I believe I am the original, first and sole (if only one inventor is listed below) or joint (if more than one inventor is listed below) inventor of the subject matter which is claimed and for which a patent is sought.

This declaration is directed to the international application of which it forms a part (if filing declaration with application).

This declaration is directed to international application No. PCT/..... (if furnishing declaration pursuant to Rule 26*ter*).

I hereby declare that my residence, mailing address, and citizenship are as stated next to my name.

I hereby state that I have reviewed and understand the contents of the above-identified international application, including the claims of said application. I have identified in the request of said application, in compliance with PCT Rule 4.10, any claim to foreign priority, and I have identified below, under the heading "Prior Applications," by application number, country or Member of the World Trade Organization, day, month and year of filing, any application for a patent or inventor's certificate filed in a country other than the United States of America, including any PCT international application designating at least one country other than the United States of America, having a filing date before that of the application on which foreign priority is claimed.

ADD R0168

Prior Applications: British Patent Application No 0012764.7 filed 26 May 2000

DEL R0168

I hereby acknowledge the duty to disclose information that is known by me to be material to patentability as defined by 37 C.F.R. § 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the PCT international filing date of the continuation-in-part application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name: ~~Gerald Rix~~

Residence: ~~United Kingdom~~
(city and either US state, if applicable, or country)

Mailing Address: ~~9 MacIntosh Way, Perth, PH1 1SL~~

Citizenship: ~~United Kingdom~~

Inventor's Signature: .....
(if not contained in the request, or if declaration is corrected or added under Rule 26*ter* after the filing of the international application. The signature must be that of the inventor, not that of the agent)

Date: .....
(of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26*ter* after the filing of the international application)

Name: GERALD HENNER RIX

Residence: UNITED KINGDOM
(city and either US state, if applicable, or country)

Mailing Address: 9 MACKINTOSH WAY
PERTH PH1 1SL

Citizenship: United Kingdom

Inventor's Signature: Gerald Rix
(if not contained in the request, or if declaration is corrected or added under Rule 26*ter* after the filing of the international application. The signature must be that of the inventor, not that of the agent)

Date: 23rd May 2001
(of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26*ter* after the filing of the international application)

☐ This declaration is continued on the following sheet, "Continuation of Box No. VIII (iv)".

14 JUN 2001 14-06-2001

PATENT COOPERATION TREATY

GST.

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

MURGITROYD & COMPANY
Scotland House
165-169 Scotland Street
Glasgow G5 8PL
GRANDE BRETAGNE

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	31.07.2002
Applicant's or agent's file reference: P25453A/RMC	IMPORTANT NOTIFICATION

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB01/02323	25/05/2001	26/05/2000

Applicant
TAYSIDE UNIVERSITY HOSPITALS NHS TRUST et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the International preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

For the purpose of deciding whether the claimed invention is patentable or not, the elected Offices may apply criteria additional to or different from the criteria on which the international preliminary examination report is based (see Articles 27(5), 33(5)). Additional criteria may include e.g. exemptions from patentability and the requirements of enabling disclosure and of clarity and support of claims.

Name and mailing address of the IPEA/	Authorized officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Ullrich, C Tel.+49 89 2399-2322

Form PCT/IPEA/416 (July 1992)

P NT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
P25453A/RMC		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB01/02323	25/05/2001	26/05/2000

International Patent Classification (IPC) or national classification and IPC
A61F2/04

Applicant
TAYSIDE UNIVERSITY HOSPITALS NHS TRUST et al.

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
24/12/2001	31.07.2002
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Hooper, M Telephone No. +49 89 2399 7438

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB01/02323

I. Basis of the report

1. With regard to the elements of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-12,14,15	as originally filed	
13	with telefax of	14/06/2002

Claims, No.:

1-21	with telefax of	16/07/2002

Drawings, sheets:

1/4,3/4,4/4	as originally filed	
2/4	with telefax of	14/06/2002

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:
   ☐ the claims, Nos.:
   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-21
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-21
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-21
	No:	Claims	

2. Citations and explanations
   see separate sheet

Re Item V

1. Reference is made to the following document.
   D1: EP-A-0 208 841

2. Document D1, which is considered to represent the closest prior art, shows (see D1, figure 1) a stent with the features of the preamble of claim 1.

   The difference between the subject-matter of claim 1 and the device of D1 is the provision of an integral valve in the tip of the lower end section. The subject-matter of claim 1 is therefore new, Article 33(2) PCT.

3. The technical problem to be solved can be regarded as providing a stent with a more reliable construction which additionally prevents reflux. This problem is solved by the provision of an integral valve. Such an integral valve is not liable to separate from the remainder of the stent during use, which might happen with valves that are subsequently attached to the device.

   None of the documents cited in the search report show such an integral valve, nor is it an obvious workshop modification for the person skilled in the art. The subject-matter of claim 1 therefore comprises an inventive step, Article 33(3) PCT, in view of the available prior art.

4. Claims 2-21 are all directly or indirectly dependent on claim 1 and are therefore also considered to be novel and inventive.

Further points to note

The description is not in conformity with the amended claims, Rule 5.1(a)(iii) PCT.

The valve leaflets will easily be pushed apart by urine passing down the stent or the guide wire onto which the stent is fed during placement.

Located about 3mm behind the valve in both 6 French gauge (1.9mm) and 4.7 French gauge (1.5mm) is a small cuff, or four studs (12) which are again moulded out of the flexible material. This cuff (9) or four studs (12) is used for the stent pusher to rest against when placing the stent over a flexible metal guide wire, this is shown in Figure 4.

Placement of the stent is facilitated by means of a conventional cystoscope using a conventional guide wire (11) passed through the urethra into the bladder, through the ureteric orifice up the ureter and into the renal pelvis under fluoroscopic control. The stent is fed onto the guide wire with the upper coil first and then pushed into place using a modified conventional stent pusher (10) which fits over the valve and rests against the cuff just behind the valve at the lower curl, thereby minimising trauma to the valve on insertion. Once the stent is in place the guide wire and stent pusher are removed.

Removal of the stent would be through the urethra using a cystoscope or alternatively from above either at the time of surgery on the kidney or with percutaneous retrieval devices.

CLAIMS

1. An indwelling ureteral stent constructed of a flexible material including a hollow elongated tubular body, the hollow elongated tubular body comprising an upper end section (1), a substantially straight middle section (2) and a lower end section (3) characterised in that the tip of the lower end section forms an integral valve (6).

2. An indwelling ureteral stent as claimed in claim 1, wherein the lower section forms a closed or substantially closed loop, such that in use the tip of the lower end section (3) of the stent does not contact the bladder lining.

3. An indwelling ureteral stent as claimed in claims 1 or 2, wherein the lower end section (3) is "G" shaped.

4. An indwelling ureteral stent as claimed in any preceding claim wherein the lower section is formed into a "G" shape and where the tip of the stent assumes the horizontal portion of the G shape.

5. An indwelling ureteral stent as claimed in claim 2, wherein the lower end section (3) is spherical in shape.

6. An indwelling ureteral stent as claimed in any

of the preceding claims wherein the lower end section (3) has a diameter of between 0.5 to 2cm.

7. An indwelling ureteral stent as claimed in any of the preceding claims wherein the upper section (1) comprises a coil, the coil being formed of between 6 to 15cm of material coiled once or twice upon itself, the coil having a resulting diameter of between 1 to 2.5cm.

8. An indwelling ureteral stent as claimed in claims 1 to 7, wherein the valve is a bicuspid valve having two leaflets (7) or a tricuspid valve having three leaflets (8).

9. An indwelling ureteral stent as claimed in claims 1 to 8, wherein the valve is provided through the moulded interlay of the flexible material such that in the closed position the leaflets of the valve lie flat against each other providing a seal which prevents fluid passing into the stent.

10. An indwelling ureteral stent as claimed in any preceding claim wherein the flexible material decreases in external diameter from the upper end section (1) to the lower end section (3).

11. An indwelling ureteral stent as claimed in claim 10, wherein the flexible material is tapered from the upper end section (1) to the

lower end section (3), such that the lower third of the middle section (2) and the totality of the lower section (3) are of a reduced diameter to that of the upper end section (1).

12. An indwelling ureteral stent as claimed in any preceding claim wherein the stent further comprises at least one projection (12) against which a stent pusher may rest.

13. An indwelling ureteral stent as claimed in claim 12 wherein the at least one projection forms a cuff (9).

14. An indwelling ureteral stent as claimed in claim 12 wherein the at least one projection consist of a plurality of studs.

15. An indwelling ureteral stent as claimed in any preceding claim wherein the stent is constructed of a flexible material.

16. An indwelling ureteral stent as claimed in claim 15, wherein the flexible material includes any composition which forms a hollow tube.

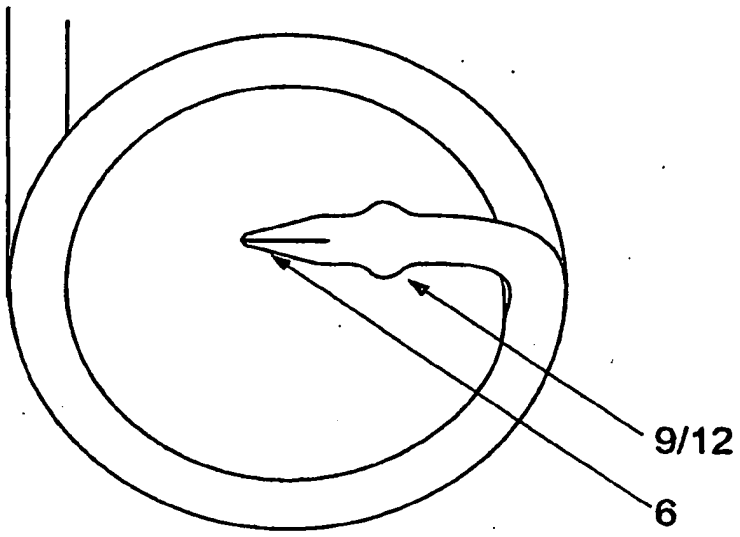
17. An indwelling ureteral stent as claimed in claim 15 wherein the flexible material has a cylindrical cross section.

18. An indwelling ureteral stent as claimed in claim 15 wherein the flexible material has a spiral, star or oval shaped cross section.

19. An indwelling ureteral stent as claimed in any of claims 15 to 18 wherein the flexible material of said stent has an external diameter in the range 1mm to 5mm.

20. An indwelling ureteral stent as claimed in any of claims 15 to 18 wherein the flexible material of said stent has an external diameter of between 1.5mm to 3mm.

21. An indwelling ureteral stent as claimed in any of claims 15 to 20 wherein the flexible material is sof flex™, endo sof™ or ultrathane™.



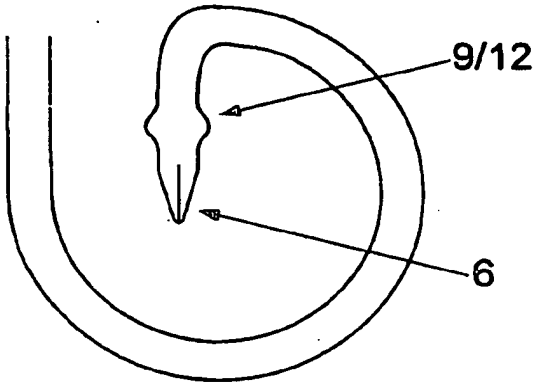


Fig. 2

TENT COOPERATION TRE[illegible]Y

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
P25453A/RMC		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB01/02323	25/05/2001	26/05/2000
International Patent Classification (IPC) or national classification and IPC A61F2/04		
Applicant TAYSIDE UNIVERSITY HOSPITALS NHS TRUST et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

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   These annexes consist of a total of 5 sheets.

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   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
24/12/2001	31.07.2002
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Hooper, M Telephone No. +49 89 2399 7438

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB01/02823

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-12,14,15	as originally filed	
13	with telefax of	14/06/2002

Claims, No.:

1-21	with telefax of	16/07/2002

Drawings, sheets:

1/4,3/4,4/4	as originally filed	
2/4	with telefax of	14/06/2002

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:
   ☐ the claims, Nos.:
   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-21
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-21
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-21
	No:	Claims	

2. Citations and explanations
   see separate sheet

R Item V

1. Reference is made to the following document.
   D1: EP-A-0 208 841

2. Document D1, which is considered to represent the closest prior art, shows (see D1, figure 1) a stent with the features of the preamble of claim 1.

   The difference between the subject-matter of claim 1 and the device of D1 is the provision of an integral valve in the tip of the lower end section. The subject-matter of claim 1 is therefore new, Article 33(2) PCT.

3. The technical problem to be solved can be regarded as providing a stent with a more reliable construction which additionally prevents reflux. This problem is solved by the provision of an integral valve. Such an integral valve is not liable to separate from the remainder of the stent during use, which might happen with valves that are subsequently attached to the device.

   None of the documents cited in the search report show such an integral valve, nor is it an obvious workshop modification for the person skilled in the art. The subject-matter of claim 1 therefore comprises an inventive step, Article 33(3) PCT, in view of the available prior art.

4. Claims 2-21 are all directly or indirectly dependent on claim 1 and are therefore also considered to be novel and inventive.

Further points to note

The description is not in conformity with the amended claims, Rule 5.1(a)(iii) PCT.